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| (54) Title: IMPROVED BETA-GLUCAN AND METHODS OF USE (57) Abstract Beta-glucan having improved properties is provided. This β -glucan preparation possesses a significantly higher molecular weight and viscosity than β -glucans prepared by standard means. These properties enable the β -glucan to be better resistant to enzymatic degradation, to exhibit a longer residence time in the gastrointestinal tract, and to extend the shelf life of food products to which it is added. | | |

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IMPROVED BETA-GLUCAN AND METHODS OF USE

This application claims priority to U.S. Provisional Application Serial No. 60/045,834, filed May 7, 1997, which is incorporated by reference herein.

5 FIELD OF THE INVENTION

This invention relates to the fields of food processing and disease management through nutrition. In particular, the invention provides an improved β -glucan for use in food processing and health promotion through
10 nutritional supplementation.

BACKGROUND OF THE INVENTION

β -glucan has been reported to have beneficial therapeutic properties. It has been shown to lower both
15 total and LDL cholesterol while not reducing the protective HDL cholesterol. It was found to help maintain a normal glucose level in the blood of diabetic patients, resulting in a decrease in insulin. It has been found beneficial in the control of obesity. A
20 feeling of satiety is achieved from the residence time in the lower intestine when β -glucan is included in the diet. The β -glucan slows the rate of gastric emptying, reduces the rate of carbohydrate absorption and it absorbs and eliminates fats in the gut. Some
25 carbohydrates are also bound and eliminated and, thus are not fully metabolized. β -glucan demonstrates good functional properties as shown in various food product developments. It has been shown to impart improvements in "mouth feel" in products with reduced fat content. It
30 also retards staling in baked goods, thereby extending shelf life by virtue of its ability to retain moisture and also by virtue of its large molecular weight, which slows water migration.

- 2 -

β -glucan obtained from conventional sources possess, in varying degrees, the utility described above. The main deficiency is the instability of conventional β -glucan to enzyme degradation. Thus, a need exists to
5 produce a β -glucan of greater stability, thereby improving its utility as a nutritional supplement and food ingredient.

SUMMARY OF THE INVENTION

10 A β -glucan having improved properties is provided in accordance with the present invention. This glucan preparation possesses a significantly higher molecular weight and viscosity than β -glucans prepared by standard means. These properties enable the glucan to be
15 better resistant to enzymatic degradation, to exhibit a longer residence time in the gastrointestinal tract and thereby enhance the physiological functional properties of conventional β -glucan, and to extend the shelf life of food products to which it is added.

20 According to one aspect of the invention, a high molecular weight β -glucan is prepared by extrusion of barley or oat flour. The β -glucan has a viscosity greater than about 1300 Braebender Units as measured in the presence of accompanying starch in the extruded
25 material. It has a viscosity of greater than about 1100 cp as measured rheometrically after digestion of the accompanying starch.

According to another aspect of the invention, a method is provided for making β -glucan from barley or
30 oats, which comprises: (1) providing barley or oat flour, preferably barley flour from waxy hull-less barley varieties; and (2) extruding the flour under a die temperature between about 100°C and 145°C, at a moisture content of between about 20% and 50%.

35 According to another aspect of the invention, a β -glucan made by the above-described method is provided.

According to another aspect of the invention,

- 3 -

the aforementioned improved β -glucan is combined with one or more other compositions to formulate a nutritional supplement for health promotion or for control of a disease condition, such as high cholesterol and/or blood glucose.

According to another aspect of the invention, the improved β -glucan is used as a food additive to improve quality and shelf life of products. In preferred embodiments it is used to replace part or all of the glycerin that is currently used in the food products.

DETAILED DESCRIPTION OF THE INVENTION

The description below relates to the improved β -glucan of the invention and methods for producing it. This β -glucan is useful for the control of certain diseases, such as hypercholesteremia and diabetes. It also has a variety of other uses, several of which are set forth below, and others of which will be apparent to one of skill in the art.

The improved β -glucan of the invention is of higher molecular weight and increased viscosity with resultant greater resistance to enzyme degradation and improved efficacy. The product is prepared by extrusion of barley or oats, as described in greater detail below. The enzyme degradation resistance and viscosity of the product may be even further improved by coating the product with a gum, such as a gum arabic.

β -glucan can be obtained from oats or barley. The barley variety preferred for use in the present invention is a waxy variety, preferably a waxy hull-less variety, such as Wanubet. However, β -glucan from any barley or oat flour is expected to display some improvement in molecular weight and viscosity, if prepared according to the methods of the present invention.

In a particularly preferred embodiment of the invention, a stabilized, fractionated barley flour

- 4 -

available from Nu-Grain Products Co, (505 West North Street, Harvey, North Dakota 58341), is used as the starting material.

5 The β -glucan is prepared from the barley or oat flour by extrusion under carefully controlled conditions. Parameters, including die temperature and moisture, must be balanced to produce an optimum product. Factors to be considered include selecting moisture and die temperature conditions sufficient to favor the formation of cross-
10 links, thereby increasing the molecular weight and viscosity so as to impart the desired functionality of the glucan, and the deactivation of β -glucanase, but not so great as to degrade the chain length of the β -glucan or cook out the starch in the flour.

15 The mechanical pressure placed on the flour during the extrusion process is a function of the moisture content, die temperature and feed rate through the extruder. The moisture level during the extrusion process is kept in the range of 20-50%, preferably 25-40%
20 by weight. The die temperature is kept in the range of 100-145°C, preferably 110-135°C.

Examples 1-5 set forth particularly preferred methods for preparing the improved β -glucan of the invention. It will be appreciated by persons skilled in
25 the art that the aforementioned pressure, temperature and moisture conditions are achieved by adjusting the extruder to certain settings, which will vary from one type of extruder to another. However, it is well within the purview of the skilled artisan to adjust those
30 conditions to achieve the pressure, temperature and moisture parameters set forth herein for production of the β -glucan of the present invention.

Using the controlled conditions described above, a high molecular weight β glucan is prepared which
35 possesses a viscosity of between about 1300 and 1800 Braebender units in the presence of the accompanying starch in the extruded material. As measured in

- 5 -

centipoise, the viscosity is at least about 1100 cp, and generally between about 1250 and 1690 cp after digestion of the accompanying starch.

5 The improvements to viscosity and molecular weight of the β -glucan described herein result in improved efficacy over β -glucan provided by conventional means. The higher molecular weight and viscosity of the β -glucan results in a longer residence time in the lower digestive system. This improves its ability to lower
10 cholesterol and to maintain normal glucose levels in the blood. This should also show benefits in weight reduction by providing longer periods of satiety. The improved resistance to enzyme degradation helps to maintain these properties. The improved efficiency
15 should also allow the β -glucan to be useful at lower dosages when employed as food additive.

 The improved β -glucan has demonstrated superior water retention properties. For instance, in meat products, the product scored superior to other
20 commercially available starches and gums specifically designed for meat applications. The superiority of the β -glucan of the invention in meat products is described in greater detail in Example 6.

 As additional examples, the same water
25 retention qualities makes the improved glucan very effective in skin creams and has been demonstrated to minimize wrinkles. Moreover, the product is expected to exceed conventional products in extending shelf life and delaying staling of baked goods.

30 The improve β -glucan of the invention is especially useful in food products that presently use glycerin in their formulations for the purpose of reducing the percentage of water. Addition of glycerin lowers the water activity of the product and its shelf
35 life is thereby extended. However, the negative result of using glycerin is the poor taste and greasy mouthfeel it imparts to the food product. Thus, while shelf life

- 6 -

is extended due to inhibition of microbial growth, the overall quality of the product is less than desirable due to the greasy quality and deterioration in flavor over time, which accompanies glycerin-supplemented food products.

The improved β -glucan of the invention, with its increased molecular weight, allows for as high as 50% reduction of glycerin in a given food product, and further serves to bind the remaining glycerin. This prevents glycerin migration and lessens its reactivity with other existing ingredients in the food.

The improved β -glucan can be used as-is, providing great flexibility in sprinkling powder onto any desired food or drink. Alternatively, it can be developed into a dietary, supplemental confection as pectin jellies or gum drops, a rather pleasant way to intake a supplement. It can also be used as an ingredient in extruded cereals, snacks, pasta, yogurt, etc., and used to replace starch, gums or fats in a food product.

The following examples are provided to describe the invention in greater detail. They are not intended to limit the invention in any way.

25

EXAMPLE 1

PREPARATION AND ANALYSIS OF IMPROVED β -GLUCAN PSS-35-1

The starting material used to produce the improved β -glucan of the invention is a commercially available (Nu-Grain Products Co.) waxy hull-less barley flour, as described in the Detailed Description, that is fractionated to give a higher content of β -glucan.

The product, referred to in this example as PSS 35-1, was prepared by extrusion, according to the following protocol.

35

Extrusion Conditions

Screw speed = 150 rpm

Mass flow rate = 150 g/min

- 7 -

Screw configuration = Pinto 1 (all forward conveying elements) IGEL - 28/28 (6) - 28/14 (7) - 20/20 (6) - 20/10 (3) - 14/14 (6) (temperatures of zones 4 and 5 (see below) were basically the controlling variables that determined the conditions used)

Moisture content = 30% (by weight)
 Die temperature = 135°C
 Die pressure = 170-190 psi
 Torque = 12%
 Barrel Temperature (zones 1-5 respectively, in degrees Centigrade) = 168, 156, 78, 56, 24

Viscosity measurements 1 - Brookfield measurements:

Instrument used: Brookfield Model DV-I
 Brookfield viscometer with #4 spindle and 5 and 10 rpm, respectively.

Procedure of preparation: we prepared 5% solutions of (1) "normal" barley flour, (2) fractionated flour as described above (as a control) and (3) extruded product PSS 35-1, in tap water. Samples were then heated to 190°F and cooled to 160°F when viscosity measurements were taken.

Findings:

| | <u>Sample</u> | <u>Viscosity</u> |
|----|-----------------|------------------|
| 25 | "normal" barley | 248 cps |
| | control | 1220 cps |
| | PSS 35-1 | 1890 cps |

Viscosity measurements 2 - Braebender measurements:

Instrument used: Braebender Visco/Amylo/Graph, Model AVI S/N 577; cooling probe in "UP".

Procedure of preparation: Fractionated flour ("control") samples and PSS 35-1 samples were prepared by mixing 35 g sample with 105 g granulated sugar and 360 g distilled water, to a final weight of 500 g. Each sample was mixed with the sugar and distilled water for about 1 min using a hand-held kitchen mixer, then placed into the

- 8 -

instrument's sample bowl. Prepared samples were heated to 30°C, held at that temperature for 60 minutes, at which time the test was stopped and measurements made. The 700 cmg sensitivity cartridge was used for
5 measurements in the instrument.

Findings:

| | <u>Sample</u> | <u>Viscosity</u> |
|--|---------------|-------------------------|
| | "control" | 0 BU (Braebender Units) |
| | PSS 35-1 | beyond 1410 BU* |

10 *the PSS 35-1 sample had not yet peaked in the 60 min time frame.

Viscosity measurements 3 - spectrophotometric measurements following removal of starch:

15 Instrument used: Rheometrics Fluids Spectrometer, model 8400, using a cone and plate geometry (diameter 5 cm, angle 0.1 radians). Each measurement was taken for 2 minutes, and was initiated 7 and 8 minutes after the starch digestion was completed.

20 Flour samples were milled on a Retch mill with a 0.5 mm sieve. The powder was suspended in 150 ml of 10mM sodium phosphate buffer, pH 6.9, and the temperature adjusted to 37°C. Optionally, the sample was cooked prior to starch digestion. For starch digestion, 8 mg
25 pancreatin (Sigma, P-1750) was added to the flour suspension, and the suspension stirred for 1 hr at 37°C.

Findings:

| | <u>Sample</u> | <u>Viscosity</u> |
|----|---------------|------------------|
| | Control | 866 cps |
| 30 | PSS-35-1 | 1470 cps |

Molecular weight measurements

Comparative molecular weights of fractionated flour ("control") and PSS 35-1 are as follows:

| | <u>Sample</u> | <u>Mol. Wt. (da)</u> |
|----|---------------|-------------------------|
| 35 | Control | 7.571 X 10 ⁵ |
| | PSS 35-1 | 4.375 X 10 ⁶ |

- 9 -

EXAMPLE 2

PREPARATION AND ANALYSIS OF IMPROVED β -GLUCAN PSS-35-3

The product, referred to in this example as PSS 35-3, was prepared by extrusion, according to the following protocol.

Starting Material and Extrusion Conditions

These were the same as for Example 1, with the following exceptions:

Die temperature = 110-111°C
Die pressure = 210-230 psi
Torque = 13%
Barrel Temperature (zones 1-5 respectively, in degrees Centigrade) = 122, 112, 68, 69, 25

Viscosity measurement - Braebender measurements:

Instrument used: Braebender Visco/Amylo/Graph, Model AVI S/N 577; cooling probe in "UP".

Procedure of preparation: As described in Example 1.

Findings:

| <u>Sample</u> | <u>Viscosity</u> |
|---------------|------------------|
| "control" | 0 BU |
| PSS 35-3 | 1350 BU |

EXAMPLE 3

PREPARATION AND ANALYSIS OF IMPROVED β -GLUCAN PSS-35-4

The product, referred to in this example as PSS 35-4, was prepared by extrusion, according to the following protocol.

Starting Material and Extrusion Conditions

These were the same as for Example 1, with the following exceptions:

Die temperature = 120-121°C
Die pressure = 180-200 psi
Torque = 10-11%
Barrel Temperature (zones 1-5 respectively, in degrees Centigrade) = 139, 130, 75, 40, 25

- 10 -

Viscosity measurement - Braebender measurements:

Instrument used: Braebender Visco/Amylo/Graph,
Model AVI S/N 577; cooling probe in "UP".

Procedure of preparation: As described in

5 Example 1.

Findings:

| <u>Sample</u> | <u>Viscosity</u> |
|---------------|------------------|
| "control" | 0 BU |
| PSS 35-4 | 1548 BU |

10

EXAMPLE 4**PREPARATION AND ANALYSIS OF IMPROVED β -GLUCAN PSS-35-7**

15 The product, referred to in this example as PSS
35-7, was prepared by extrusion, according to the
following protocol.

Starting Material and Extrusion Conditions

These were the same as for Example 1, with the
following exceptions:

20

Moisture content = 47% (weight basis)

Die temperature = 120°C

Die pressure = 60-70 psi

Torque = 14%

25

Barrel Temperature (zones 1-5 respectively, in
degrees Centigrade) = 150, 136, 69, 27, 25

Viscosity measurement - Braebender measurements:

Instrument used: Braebender Visco/Amylo/Graph,
Model AVI S/N 577; cooling probe in "UP".

30

Procedure of preparation: As described in

Example 1.

Findings:

| <u>Sample</u> | <u>Viscosity</u> |
|---------------|------------------|
| "control" | 0 BU |
| PSS 35-7 | 1710 BU |

35

- 11 -

EXAMPLE 5

PREPARATION AND ANALYSIS OF IMPROVED β -GLUCAN PSS 35-8

The product, referred to in this example as PSS 35-8, was prepared by extrusion, according to the following protocol.

Starting Material and Extrusion Conditions

These were the same as for Example 1, with the following exceptions:

Moisture = 47% (by weight)

Die temperature = 128°C

Die pressure = 250-60 psi

Torque = 14%

Barrel Temperature (zones 1-5 respectively, in degrees Centigrade) = 160, 136, 69, 27, 24

Viscosity measurement - Braebender measurements:

Instrument used: Braebender Visco/Amylo/Graph, Model AVI S/N 577; cooling probe in "UP".

Procedure of preparation: As described in Example 1.

Findings:

| <u>Sample</u> | <u>Viscosity</u> |
|---------------|------------------|
| "control" | 0 BU |
| PSS 35-8 | 1650 BU |

EXAMPLE 6

USE OF β -GLUCAN IN MEAT PRODUCTS

This example illustrates the superiority of β -glucan for use in meat products. Re-formed turkey patties were formulated using the following ten products. Each formulation was evaluated and rated for its absorption qualities, texture and organoleptic qualities, according to standard methods.

- 1) starch acetate flake
- 2) cellulose acetate micro fiber
- 3) cellulose acetate flake
- 4) Solka Floc
- 5) Viscarine #389

- 12 -

- 6) Gelcarine #911
- 7) Gelcarine #621-ME
- 8) Firmtex
- 9) β -glucan (3%)
- 5 h) β -glucan (5%)

The absorption qualities were rated as follows:

- 1) β -glucan 5% . . . best
- 2) Firmtex close second
- 10 3/4) Viscarine #389 and β -glucan 3%
(negligible difference)
- 5/6) Gelcarine and Solka Floc
(negligible difference)
- 7) starch acetate flake
- 15 8) cellulose acetate micro fiber
- 9) cellulose acetate flake
- 10) Gelcarine #621-ME

20 The textural and organoleptic qualities were rated as follows:

- 1) β -glucan 5% . . . notably best
- 2) β -glucan 3%
- 3) Firmtex
- 4) starch acetate flake
- 25 5) Solka Floc
- 6) Viscarine
- 7) Gelcarine #911
- 8) Gelcarine #621-ME
- 9) cellulose acetate micro fiber
- 30 10) cellulose acetate flake

The present invention is not limited to the embodiments described herein, but may be varied and modified within the scope of the appended claims.

- 13 -

What is claimed is:

1. β -glucan having a viscosity greater than about 1100 centipoise.
- 5 2. The β -glucan of claim 1, having a viscosity between about 1250 and 1690 centipoise.
3. The β -glucan of claim 1, prepared from
10 barley.
4. The β -glucan of claim 4, prepared from a waxy, hull-less barley variety.
- 15 5. A nutritional supplement comprising the β -glucan of claim 1.
6. A food additive comprising the β -glucan of claim 1.
- 20 7. A method of preparing β -glucan from barley or oats, comprising
 - a) preparing flour from the barley or
oats,
 - 25 b) extruding the flour under a die temperature between about 100°C and 145°C, with a moisture content of between about 20% and 50% by weight; and
 - 30 c) recovering the β -glucan.
8. The method of claim 7, wherein the barley is a waxy, hull-less variety.
9. The method of claim 7, wherein the die
35 temperature is between about 110°C and 135°C and the moisture content is between about 25% and 40% by weight.

- 14 -

10. The method of claim 9, wherein the die temperature is 135°C and the moisture content is about 30% by weight.

5 11. β -glucan prepared by the method of claim 7.

12. A nutritional supplement comprising the β -glucan of claim 11.

10

13. A food additive comprising the β -glucan of claim 11.

15 14. A method of preparing β -glucan from a β -glucan enriched fraction of flour from waxy, hull-less barley, which comprises extruding the flour at a die temperature of 110-135°C and moisture content of 25-40% by weight, and recovering the β -glucan.

20 15. β -glucan prepared by the method of claim 14.

16. A nutritional supplement comprising the β -glucan of claim 15.

25

17. A food additive comprising the β -glucan of claim 15.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/09333

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :C07H 1/00, 1/06; A23G 3/00

US CL :596/123.12, 124, 127; 426/658; 514/54

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 536/123.12, 124, 127; 426/658; 514/54

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, MAYA, HCAPLUS, CABA, WPIDS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| Y | JP 5-23193 A (KOTANI ET AL.) 02 February 1993, see entire document. | 1-6, 11-13, and 15-17 |
| Y | JP 7-119243 B2 (KANEBO LTD.) 20 December 1995, see entire document. | 1-6, 11-13, and 15-17 |
| X | US 5,614,242 A (FOX) 25 March 1997, see entire document. | 1-6, 11-13, and 15-17 |
| Y | YOON et al. Evaluation of Selected Barley Cultivars and Their Fractions for Beta-Glucan Enrichment and Viscosity. Cereal Chemistry. February 1995, Vol. 72, No. 2, pages 187-190, see entire document. | 1-6, 11-13, and 15-17 |

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | * Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| Y | TEMELLI, Feral. Extraction and Functional Properties of Barley beta-Glucan as Affected by Temperature and pH. Journal of Food Science. 1997, Vol. 62, No. 6, pages 1194-1201, see especially pages 1194-1196. | 1-6, 11-13 and 15-17 |